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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,947	05/02/2001	Stephen Ainsworth	CSI-2016CPI	6172

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EXAMINER

LINDSEY, RODNEY M

ART UNIT	PAPER NUMBER
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3765

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/847,947		Applicant(s) AINSWORTH ET AL.	
	Examiner Rodney M. Lindsey		Art Unit 3765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 29 June 2004 and 28 July 2004.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 4,8,9,15-21,24,27-29,35-53,56-59 and 64-113 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) 4/21,21,24/41,41-53,56-59 and 64-111 is/are allowed.

6) ☒ Claim(s) 4/8,4/9,4/15,4/16,4/17,4/19,4/20,8,9,15-20,24/20,24/27,24/28,24/29,24/35,24/36,24/37,24/38,24/39,24/40,27,28,29,35-40,112 and 113 is/are rejected.

7) ☒ Claim(s) 24/21 is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 29 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/28/4</u> .	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____.
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DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claims 15, 16, 20, 27, 35, 36 and 40 is withdrawn in view of the newly discovered reference(s) to Berg et al. '015 and Berg et al. '048. Rejections based on the newly cited reference(s) follow.
2. Claims 112 and 113 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
3. Claims 4/21, 21, 24/41, 41-53, 56-59, 64-111 are allowed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 112 and 113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 112, line 2 "said tissue", line 5 "said piercing" and line 14 "said tissue" and in claim 113, line 6 "said piercing", all, have no antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. Claims 4/8, 4/9, 4/15, 4/16, 4/17, 4/19, 4/20, 8, 9, 15-20, 24/20, 24/28, 24/29, 24/35, 24/36, 24/37, 24/38, 24/39, 24/40, 28, 29, 35-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Berg et al. '015. With respect to claims 8, 15, 16, 17, 19 and 20 note Figures 1-8 and 24, and the stopper at 14 opposed to the proximal members 14 on opposite sides of the portion 16 and the fastened configuration of Figures 6, 8 and the open configuration of Figure 7 and the distally oriented ends of Figures 6, 8 and with the number of proximal members 14 equaling the number of distal members 14. With respect to claim 9 note the symmetric arrangement of the members 14. With respect to claim 15 note the wire 90 equivalent to suture as claimed. With respect to claim 16 note the wire 90 equivalent to a gripping device or clip as claimed. With respect to claims 17 and 18 note tube 40 equivalent to a restraint mechanism. With respect to claim 19 note tube 40 equivalent to a restraint mechanism and note that the restraint mechanism inherently releases the fastener when the fastener is pulled from the restraint mechanism. With respect to claim 20 note tube 40 equivalent to a restraint mechanism and note that the restraint mechanism embodying all the structure of the instant restraint mechanism inherently releases the fastener when squeezed. With respect to claims 4/8, 4/9, 4/15, 4/16, 4/17, 4/19, 4/20, 24/20, 24/28, 24/29, 24/35, 24/36, 24/37, 24/38, 24/39 and 24/40 note the use of nitinol (see column 2, line 3). With respect to claim 28 note Figure 24 and the restraint mechanism equivalent to wire 90 and the equal number of proximal and distal members 14. With respect to claim 29 note the symmetry of the fastener shown in Figure 24. With respect to claim 35 note Figure 24 and the wire 90 equivalent to a suture restraint mechanism. With respect to claim 36 note Figure 24 and the wire 90 equivalent to a clip restraint mechanism. With respect to claims 37 and 38 note Figures 1-8 and the tube 40 equivalent to the restraint

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mechanism after release of one set of members 14. With respect to claim 39 note Figures 1-8 and the tube 40 equivalent to the restraint mechanism after release of one set of members 14 and note that the tube 40 inherently releases the fastener when the fastener is pulled from the restraint mechanism. With respect to claim 40 note Figures 1-8 and the tube 40 equivalent to the restraint mechanism after release of one set of members 14 and note that the restraint mechanism embodying all the structure of the instant restraint mechanism inherently releases the fastener when squeezed.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 24/27 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al. '015 in view of Berg et al. '048. Berg et al. '015 shows in Figure 24 distal and proximal members 14 and a wire 90 equivalent to a restraint mechanism for the proximal members 14. Berg et al. '015 does not teach the distal member comprising a disk shaped member. Berg et al. '048 teach old the use of a distal stopper member 82 in the shape of a disk. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the disk 82 of Berg et al. '048 for the distal members 14 to achieve a like result of forming a stop member for engagement of tissue. With respect to claim 24/27 note the use of nitinol in Berg et al. '015 (see column 2, line 3).

Double Patenting

10. Applicant is advised that should claim 4/20 be found allowable, claim 24/20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

11. Claim 24/21 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 4/21. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Response to Arguments

12. Applicant's arguments with respect to claims 4/8, 4/9, 4/15, 4/16, 4/17, 4/19, 4/20, 8, 9, 15-20, 24/20, 24/27, 24/28, 24/29, 24/35, 24/36, 24/37, 24/38, 24/39, 24/40, 27, 28, 29, 35-40, 112 and 113 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

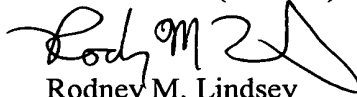
13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note particularly, the restrained fasteners of Peterson et al., Yencho et al. and King et al. at 91''.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney M. Lindsey whose telephone number is (703) 305-7818. The examiner can normally be reached on M-F (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John J. Calvert can be reached on (703) 305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Rodney M. Lindsey
Primary Examiner
Art Unit 3765

rml